



## A Single Development Pathway Can Improve Patient Access to Generic Drugs

It's time for the U.S. to remove an unnecessary roadblock to competition for generic prescription drugs. Regulators on both sides of the Atlantic are often doing the same job at the same time, causing unnecessary costs and delays in bringing affordable generics to the marketplace.

The Food and Drug Administration (FDA) and its European regulatory counterparts work tirelessly to ensure that generic drugs meet the same strict standards for purity, quality, strength, and stability as their branded counterparts. Improving regulatory coordination can avoid unnecessary duplication of product development, regulatory review, and approval efforts; as well as help alleviate significant delays in getting safe, effective and more affordable medicines to patients.

We need a joint regulatory strategy where generic drug guidances and guidelines are coordinated and adopted by both the E.U. and the U.S. regulatory authorities. Thus, generic drug manufacturers can follow a single development pathway leading to greater consumer access to affordable generic medicines.

As U.S. and E.U. negotiators continue to hammer out the details of a trade deal in the Trans-Atlantic Trade and Investment Partnership (TTIP), this single development pathway for generics would be a clear winner for American consumers. Drugs that have already undergone strict regulatory review and approval processes, including clinical trials where

appropriate (for example in the more complex products), in either Europe or the U.S. shouldn't need to hit the roadblock of another lengthy, costly and unnecessary approval process. Instead, these safe and proven medicines should be made readily available to patients in both regions, each who face the harsh economic realities of purchasing prescription drugs.

Congress should urge the U.S. Trade Representative to forcefully argue to include a mandate in TTIP requiring the FDA and its European regulatory counterparts to advance a single development regulatory pathway for generic medicines. A successful single development pathway for generic medicines would foster competition and lead to more affordable medicines for the American people.

Generic drugs are nearly 9 of every 10 prescriptions dispensed each day but a mere 28 percent of the amount spent on prescriptions. Generics are saving the American healthcare system \$5 billion per week. Yet the current system can do more to expand patient access to these important medicines.

Now, more than ever, Americans are looking to Washington for answers to problems in our healthcare system. The Generic Pharmaceutical Association is proposing five concrete policy prescriptions, including this one—creating a single pathway for the approval of generic drugs—that policymakers can enact today to spur competition, expand access and increase savings for millions of Americans.

